

Application No. 10/690,987  
September 30, 2008 Reply To Office Action

### REMARKS

#### Summary of Office Action

Claims 29-50 are pending in this application.

The Examiner rejected claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Szapiro et al. U.S. Patent No. 5,785,683 (hereinafter "Szapiro").

Claims 37-39, 41, 43, and 44 were rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Szapiro in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30, 40, and 46 were rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And claims 32, 34-36, 42, 45, and 47-50 were rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in further view of Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

#### Summary of Applicants' Reply

Applicants have amended independent claim 39 to more particularly point out and distinctly claim the subject matter that applicants regard as the invention.

No new matter has been added.

Reconsideration of this application in view of the amendments and following remarks is respectfully requested.

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Rejections of Claims 29, 31, 33, 34, 45, 47, 49, and 50 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, 34, 45, 47, 49, and 50 have been rejected under 35 U.S.C.

§ 103(a) as being obvious from Forsberg in view of Szapiro.

These rejections are respectfully traversed.

Independent Claim 29

Independent claim 29 requires “filling the front compartment of the chamber with a dry medicament portion through the front end of the chamber” (emphasis added). As described in applicants’ specification, the needle-end of applicants’ chamber (i.e., the front end as recited in claim 29) advantageously “is not significantly narrowed or tapered. Such ... [a] configuration permits direct access to the dry portion 152 of chamber 150 for easy loading” (page 9, paragraph 39).

The Examiner said that it would have been obvious to use the seal and barrel structure of Szapiro with the loading method of Forsberg (June 30, 2008 Office Action, page 3).

Applicants respectfully submit that (1) the combination of Forsberg’s method and Szapiro’s barrel structure is not at all obvious and (2), if combined, would not work as required by claim 29.

As shown in all of Szapiro’s FIGS. 1-7, the needle-end of main body 1 has a conically-shaped injection nozzle 5 at its upper base 4. The opening of nozzle 5 is very, very small (compare with the opening at lower base 2 of main body 1).

Szapiro does not disclose or suggest in any way the manner in which its upper chamber 16 and lower chamber 11 are to be loaded with a powdered drug and diluent, respectively.

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Applicants therefore submit that Szapiro's upper chamber 16 is not intended to be filled with solid material M through nozzle 5.

Applicants further submit that a person of ordinary skill in the art would not be motivated in any way to apply Forsberg's method to the disposable syringe of Szapiro by attempting to load a dry medicament through the tiny opening in nozzle 5 in view of the much larger opening at lower base 2 of Szapiro's main body 1.

Accordingly, the combination of Forsberg and Szapiro does not result in applicants' invention as defined in independent claim 29 and, therefore, claim 29 is not obvious from that combination and should be allowable.

If the Examiner continues to assert that loading a solid material M through nozzle 5 would not render the combination of Forsberg and Szapiro unsatisfactory, applicants respectfully request that the Examiner cite evidence to support the feasibility of such an impractical, if not impossible, method of loading upper chamber 16 -- particularly when loading from the much larger opening at lower base 2 is such an obvious alternative.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Moreover, dependent claim 33 requires sealing the rear end of the chamber by installing a plunger. Szapiro, in contrast, seals the rear end (lower base 2) of its disposable syringe with a plug 9 -- not a plunger. Szapiro's plunger 7 divides main body 1 into upper chamber 16 and lower chamber 11. Thus, dependent claim 33 is also not obvious from the combination of Forsberg and Szapiro for that reason.

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Independent Claim 45

Independent claim 45 requires that the open front end and the open rear end of the chamber each have an open mouth configuration.

As discussed above, Szapiro's disposable syringe has an open lower base 2 but a conically-shaped injection nozzle 5 at its upper base 4. This structure "defines the coupling for the plugging cone of the injection needle" (Szapiro column 3, lines 21-22). As shown in all of Szapiro's FIGS. 1-7, outlet nozzle 5 plainly does not have an open mouth configuration.

Claim 45 is therefore not obvious from the combination of Forsberg and Szapiro and should thus be allowable.

Dependent claims 47, 49, and 50, which depend from independent claim 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

In sum, applicants respectfully request that the rejections of claims 29, 31, 33, 34, 45, 47, 49, and 50 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg and Szapiro in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

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### Independent Claim 39

Independent claim 39 has been amended to require the open front end of the chamber to have an open mouth configuration. Support for this amendment is found, *e.g.*, in FIG. 9 and on specification page 17, paragraph 68: "As shown in FIG. 9, the chamber has an 'open mouth' configuration .... [making] it ... easier to load the dry component of the medicament."

As discussed above, Szapiro's main body 1 has no such opening at upper base 4, but instead has injection nozzle 5.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particulate-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Szapiro.

The combination of Forsberg, Szapiro, and Odell therefore does not render amended claim 39 obvious and, thus, claim 39 should be allowable.

For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Moreover, dependent claim 44 requires sealing the rear end of the chamber by installing a plunger. Szapiro, in contrast, seals the rear end (lower base 2) of its disposable syringe with a plug 9 -- not a plunger. Szapiro's plunger 7 divides main body 1 into upper chamber 16 and lower chamber 11. Thus, dependent claim 44 is also not obvious from the combination of Forsberg, Szapiro, and Odell for that reason.

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Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. § 103(a) be withdrawn.

Rejections of Claims 30, 32, 34-36, 40, 42, and 45-50 Under 35 U.S.C. § 103(a)

Claims 30, 40, and 46 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in view of Geprägs. Claims 32, 34-36, 42, 45, and 47-50 have been rejected under 35 U.S.C. § 103(a) as being obvious from Forsberg/Szapiro/Odell in further view of Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Szapiro as discussed above with respect to independent claims 29, 39, and 45.

Thus, any combination of Forsberg, Szapiro, Odell, Geprägs, and Tanaka does not render obvious independent claims 29, 39, or 45.

For at least these reasons, dependent claims 30, 32, 34-36, 40, 42, and 46-50, which depend directly or indirectly from one of claims 29, 39, or 45, should also be allowable (*i.e.*, dependent claims are allowable if their independent claim is allowable).

Moreover, dependent claim 35, which depends from independent claim 29, requires the dry medicament portion to be tablet sized and adapted to fit through the front end of the chamber. Applicants respectfully submit that no "tablet" (as a person of ordinary skill in the

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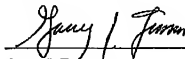
art would understand that word) can be adapted to fit through injection nozzle 5 of Szapiro's disposable syringe. Thus, dependent claim 35 is also not obvious from any combination of the cited references for that reason.

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40, 42, and 45-50 under 35 U.S.C. § 103(a) be withdrawn.

#### Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,



Garry J. Tuma  
Registration No. 40,210  
Attorney for Applicants

JONES DAY  
Customer No. 20583  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939